

and the lower section, enabling the annulus stent to form a compatible fit with the edges of an aperture.

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46. The annulus stent of claim 45 wherein the upper section of the centralized vertical extension comprises a slot, where the slot 18 forms an orifice through the upper section.
  47. The annulus stent of claim 46 wherein the slot is positioned within the upper section such that it traverses the longitudinal axis of the upper section.
  48. The annulus stent of claim 47, wherein the slot is sized and shaped to accommodate sutures, tension bands, or staples.

#### REMARKS

Entry and consideration of this amendment is respectfully requested.

The specification has been amended to correct numerous informalities, spelling and grammatical errors. Accordingly, no new matter is entered by amendment.

Claims 1-44, originally pending in parent application serial number 09/947,078 have been cancelled and claims 45-48 have been added to this continuation application.

Applicants await an examination on the merits.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

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Respectfully submitted,

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**APPENDIX TO PRELIMINARY AMENDMENT  
VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Paragraph starting at page 1, line 12 and extending to line 17:

[002] The invention generally relates to a surgical method of intervertebral disc wall [reconstruction with a related annulus stent augmenting the]reconstruction. The invention also relates to an annular repair device, or stent, for annular disc repair. The effects of said reconstruction are restoration of disc wall integrity and reduction of the failure rate (3-21%) of a common surgical procedure (disc fragment removal or discectomy). This surgical procedure is performed about 390,000 times annually in the United States.

Paragraph starting at page 2, line 9 extending to line 20:

[005] [As people age, the annulus tends to thicken, desiccate, and become more rigid. The nucleus pulposus, in turn, becomes more viscous and less fluid and sometimes even dehydrates and contracts. The annulus also becomes susceptible to fracturing or fissuring. These fractures tend to occur all around the circumference of the annulus and can extend from both the outside of the annulus inwards, and the interior outward. Occasionally, a fissure from the outside of the annulus meets a fissure from the inside and results in a complete rent or tear through the annulus fibrosis. In situations like these, the nucleus pulposus may extrude out through the annulus wall. The extruded material, in turn, can impinge on the spinal cord or on the spinal nerve rootlet as it exits through the intervertebral disc foramen, resulting in a condition termed ruptured disc or herniated disc] The aging process contributes to gradual changes in the intervertebral discs. The annulus loses much of its flexibility and resilience, becoming more dense and solid in composition. The aging annulus is also marked by the appearance on propagation of cracks or fissures in the annular wall. Similarly, the nucleus dessicates, increasing viscosity and thus losing its fluidity. In combination, these features of the aged intervertebral discs result in less dynamic stress distribution because of the more viscous nucleus pulposus, and less ability to withstand localized stresses by the annulus fibrosus due to its dessication, loss of flexibility and the presence of fissures. Occasionally fissures may form rents through the annular wall. In these instances, the nucleus pulposus is urged outwardly from the subannular space through a rent, often into the spinal column. Extruded nucleus pulposus can, and often does, mechanically press on the spinal cord or spinal nerve rootlet. This painful condition is clinically referred to as a ruptured or herniated disc.

Paragraph starting at page 2, line 21 and extending to page 3, line 8:

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[006] In the event of annulus rupture, the [inner-nucleus component] subannular nucleus pulposus migrates along the path of least resistance forcing the fissure to open further, allowing migration of the nucleus pulposus through the wall of the disc, with resultant nerve compression and leakage of chemicals of inflammation into the space around the adjacent nerve roots supplying the extremities, bladder, bowel and genitalia. The usual effect of nerve compression and inflammation is intolerable back or neck pain, radiating into the extremities, with accompanying numbness, weakness, and in late stages, paralysis and muscle atrophy, and/or bladder and bowel incontinence. Additionally, injury, disease or other degenerative disorders may cause one or more of the intervertebral discs to shrink, collapse, deteriorate or become displaced, herniated, or otherwise damaged and compromised.

Paragraph starting at page 4, line 2 and extending to line 4:

[010] The present invention provides methods and related materials for reconstruction of the [disk] disc wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs. In accordance with the invention, an annulus stent is disclosed for repair of an intervertebral disc annulus, comprising lateral extensions from a vertical body.

Paragraph starting at page 4, line 5 and extending to line 8:

[011] In [a preferred form] an exemplary embodiment, one or more mild biodegradable surgical sutures are placed at about equal distances along the sides of a pathologic aperture in the ruptured disc wall (annulus) or along the sides of a surgical incision in the [weakened, thinned disc annulus] annular wall, which may be weakened or thinned.

Paragraph starting at page 4, line 15 and extending to line 20:

[014] In another embodiment, the method can be augmented by creating a subannular barrier in and across the aperture by placement of a patch of human muscle fascia (the membrane covering the muscle) or any other [autograft or allograft] autograft, allograft, or xenograft acting as a bridge [in and across the aperture] or a scaffold, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture.

Paragraph starting at page 5, line 16 and extending to line 9:

[016] Having demonstrated that human muscle fascia is adaptable for annular reconstruction, other biocompatible membranes can be employed as a bridge, stent, patch or barrier to subsequent migration of the disc nucleus through the aperture. Such biocompatible materials may be, for example, a medical grade

biocompatible fabrics, biodegradable polymeric sheets, or form fitting or non-form fitting fillers for the cavity created by removal of a portion of the disc nucleus pulposus in the course of the disc fragment removal or discectomy. The prosthetic material can be placed in and around the intervertebral space, created by removal of the degenerated disc fragments.

Paragraph at page 5, line 14:

[017] [Figure] FIG. 1 shows a perspective view of [the] an illustrative embodiment of an annulus stent.

Paragraph at page 5, line 12:

[018] [Figure] FIG. 2 shows a front view of the annulus stent of FIG. 1.

Paragraph at page 5, line 13:

[019] [Figure] FIG. 3 shows a side view of the annulus stent of FIG. 1.

Paragraph starting at page 5, line 14 extending to line 15:

[020] [Figure] FIGs. 4A-4C show a front view of [various alternative embodiments of the] alternative illustrative embodiments of an annulus stent.

Paragraph starting at page 5, line 16 extending to line 17:

[021] [Figure] FIGs. 5A-5B [shows the alternative embodiment of a pyramid shaped] show the alternative embodiment of a further illustrative embodiment of an annulus stent.

Paragraph starting at page 5, line 18 extending to line 19:

[022] [Figure] FIGs. 6A-6B [shows the alternative embodiment of a coned shaped] show the alternative embodiment of a further illustrative embodiment of an annulus stent.

Paragraph starting at page 5, line 20 extending to line 21:

[023] [Figure] FIG. 7 shows [the] a primary closure of [the] an opening in the disc annulus[, without an intervertebral or subannular stent].

Paragraph starting at page 5, line 22 extending to line 23:

[024] [Figure] FIGs. 8A-8B [shows the] show a primary closure with a stent [in generic form].

Paragraph starting at page 6, line 1 and extending to line 2:

[025] [Figure] FIG. 9 shows a method of suturing [the] an annulus stent into the disc annulus, utilizing sub-annular fixation points.

Paragraph starting at page 6, line 3 extending to line 4:

[026] [Figure] FIGs. 10A-10B show [the] a further illustrative embodiment of an annulus stent with flexible bladder being expanded into the disc annulus.

Paragraph starting at page 6, line 5 extending to line 6:

[027] [Figure] FIGs. 11A-11D show [the] an annulus stent being inserted into the disc annulus.

Paragraph starting at page 6, line 7 extending to line 8:

[028] [Figure] FIGs. 12A-12B show [the] an annulus stent with [the] a flexible bladder being expanded by injection.

Paragraph starting at page 6, line 11 and extending to line 13:

[029] [The present invention provides methods and related materials for reconstruction of the disk wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs.] Reference will now be made in detail to an illustrative embodiment of the invention, which appears in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

Paragraph starting at page 6, line 14 and extending to line 23:

[030] In one embodiment of the present invention, as shown in [Figure] FIG. 7, a damaged annulus 42 is repaired by use of surgical sutures 40. One or more surgical sutures 40 are placed at about equal distances along the sides of a pathologic aperture 44 in the [ruptured] annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 [in such a fashion] so that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue (e.g., fibroblasts) crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable, but permanent non- biodegradable may be utilized.

Paragraph starting at page 7, line 1 extending to line 10:

[031] Additionally, to repair a weakened or thinned wall of a disc annulus 42, a surgical incision is made along the weakened or thinned region of the annulus 42 and one or more surgical sutures 40 [are] can be placed at about equal distances [along the sides of] laterally from the incision. Reapproximation or closure of the incision is accomplished by tying the sutures 40 [in such a fashion] so that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable, but permanent non-biodegradable materials may be utilized.

Paragraph starting at page 7, line 11 extending to page line 16:

[032] In an alternative embodiment, the method can be augmented by the placement of a patch of human muscle fascia or any other autograft, allograft or xenograft in and across the aperture 44. The patch acts as a bridge in and across the aperture 44, providing a platform for traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus 42, prior to closure of the aperture 44.

Paragraph starting at page 7, line 17 extending to line 22:

[033] In a further embodiment, as shown in [Figure 8] FIGs. 8A-B, a biocompatible membrane can be employed as an annulus stent 10, being placed in and across the aperture 44. The annulus stent 10 acts as a bridge in and across the aperture 44, providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus, prior to closure of the aperture 44.

Paragraph starting at page 7, line 23 and extending to page 8, line 4:

[034] In [a preferred] an illustrative embodiment, as shown in [Figures] FIGs. 1-3, the annulus stent 10 comprises a centralized vertical extension 12, with an upper section 14 and a lower section 16. The centralized vertical extension 12 can be trapezoid in shape through the width and may be from about 8mm -12mm in length.

Paragraph starting at page 8, line 4 extending to line 10:

[035] Additionally, the upper section 14 of the centralized vertical extension 12 may be any number of different shapes, as shown in [Figures] FIGs. 4A and 4B, with the sides of the upper section 14 being curved or with the upper section 14 being circular in shape. Furthermore, the annulus stent 10 may contain a recess between the upper section 14 and the lower section 16, enabling the annulus stent 10 to form a compatible fit with the edges of the aperture 44.

Paragraph starting at page 8, line 11 extending to line 17:

[036] The upper section 14 of the centralized vertical extension 12 can comprise a slot 18, where the slot 18 forms an orifice through the upper section 14. The slot 18 is positioned within the upper section 14 such that [14] it traverses the upper section's 14 longitudinal axis. The slot 18 is of such a size and shape that sutures, tension bands, staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent 10 to the disc annulus [44] 42.

Paragraph starting at page 8, line 18 extending to line 23:

[037] In an alternative embodiment, the upper section 14 of the centralized vertical extension 12 may be perforated. The perforated upper section 14 contains a plurality of holes [which] that traverse the [upper section's 14] longitudinal axis of upper section 14. The perforations are of such a size and shape that sutures, tension bands, staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent 10 to the disc annulus [44] 42.

Paragraph starting at page 9, line 1 extending to line 12:

[038] The lower section 16 of the centralized vertical extension 12 can comprise a pair of lateral extensions, a left lateral extension 20 and a right lateral extension 22. The lateral extensions 20 and 22 comprise an inside edge 24, an outside edge 26, an upper surface 28, and a lower surface 30. The lateral extensions 20 and 22 can have an essentially constant thickness throughout. The inside edge 24 is attached to [the lower section 16] and is about the same length as the lower section 16. The outside edge 26 can be about 8mm - 16mm 8mm-16mm in length. The inside edge 24 and the lower section 16 meet to form a horizontal plane, essentially perpendicular to the centralized vertical extension 12. The upper surface 28 of the lateral extensions 20 and 22 can form an angle [of] from about 0°-60° below the horizontal plane. The width of the annulus stent 10 may be from about 3mm-5mm.

Paragraph starting at page 9, line 13 extending to line 15:

[039] Additionally, the upper surface 28 of the lateral extensions 20 and 22 may be barbed for fixation to the inside surface of the disc annulus [40] 42 and to resist expulsion through the aperture 44.

Paragraph starting at page 9, line 16 extending to line 18:

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[040] In an alternative embodiment, as shown in [Figure] FIG. 4B, the lateral extensions 20 and 22 have a greater thickness at the inside edge 24 than at the outside edge 26.

Paragraph starting at page 9, line 19 extending to line 21:

[041] In [a preferred] an illustrative embodiment, the annulus stent 10 is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well know in the art.

Paragraph starting at page 9, line 22 and extending to page 10, line 11:

[042] For example, the annulus stent 10 may be made from:  
a porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus fibrosus as disclosed in, for example, U.S.U. S. Patent Nos. 5,108,438 (Stone) and 5,258,043 (Stone);  
a strong network of inert fibers intermingled with a bioresorbable (or [bosabsorbable] bioabsorbable) material which attracts tissue ingrowth as disclosed in, for example, U.S. Patent No. 4,904,260 (Ray et al.);  
a biodegradable substrate as disclosed in, for example, U.S. Patent No. 5,964,807 (Gan et al.); or  
[a] an expandable polytetrafluoroethylene (ePTFE), as used for conventional vascular grafts, such as those sold by W.L. Gore and Associates, Inc. under the trademarks GORE-TEX and PRECLUDE, or by Impra, Inc. under the trademark IMPRA.

Paragraph starting at page 10, line 15 extending to line 19:

[044] Additionally, the annulus stent 10 may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica-based materials [which] that assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

Paragraph starting at page 10, line 20 and extending to page 11, line 2:

[045] In further embodiments, as shown in [Figures 5-6] FIGs. 5AB-6AB, the left and right lateral extensions 20 and 22 join to form a solid pyramid or cone. Additionally, the left and right lateral extensions 20 and 22 may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral extensions 20 and 22 to be compressed for insertion into aperture 44, then to expand conforming to the shape of the annulus'42 inner wall.

Paragraph starting at page 11, line 3 extending to line 10:

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[046] Alternatively, a compressible core may be attached to the lower surface 30 of the lateral extensions 20 and 22, forming a pyramid, cone, trapezoid, wedge, or bullet shape. The compressible core may be made from one of the biocompatible or bioresorbable resilient foams well known in the art. The core can also comprise a fluid-expandable membrane, e.g., a balloon. The compressible core allows the lateral extensions 20 and 22 to be compressed for insertion into aperture 44, then to expand conforming to the shape of the annulus' 42 inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

Paragraph starting at page 11, line 11 extending to line 17:

[047] In [a preferred] an illustrative method of use, as shown in [Figures 10A-10D] FIGs. 11A-D, the lateral extensions 20 and 22 are compressed together for insertion into the aperture 44 of the disc annulus [40] 42. The annulus stent 10 is then inserted into the aperture 44, where the lateral extensions 20, 22 expand. In an [20 and 22 expand, with] expanded configuration, the upper surface 28 [contouring to] can substantially conform to the contour of the inside surface of the disc annulus [40] 42. The upper section 14 is positioned within the aperture 44 so that the annulus stent 10 may be secured to the disc annulus [40] 42, using means well known in the art.

Paragraph starting at page 11, line 18 and extending to page 12, line 4:

[048] In an alternative method, where the length of the aperture 44 is less than the length of the outside edge 26 of the annulus stent 10, the annulus stent 10 [must] can be inserted laterally into the aperture 44. The lateral extensions 20 and 22 are compressed, and the annulus stent 10 is can then be rotated inside the disc annulus [40] 42, such that the upper section 14 [is pulled] can be held back through the aperture 44. The lateral extensions 20 and 22 are then allowed to expand, with the upper surface 28 contouring to the inside surface of the disc annulus [40] 42. The upper section 14 [is] can be positioned within, or proximate to, the aperture 44 in the subannular space such that the annulus stent 10 may be secured to the disc annulus, using means well known in the art.

Paragraph starting at page 12, line 5 extending to line 23:

[049] In an alternative method of securing the annulus stent 10 in the aperture 44, as shown in [Figure] FIG. 9, a first surgical screw 50 and second surgical screw 52, with eye holes 53 located at the top of the screws 50 and 52, are opposingly inserted into the adjacent vertebrae 54 and 56 below the annulus stent 10. After insertion of the annulus stent 10 into the aperture 44, a suture 40 is passed down through the disc annulus [40] 42, adjacent to the aperture 44, through the eye hole 53 on the first screw 50 then back up through the disc

annulus [40] 42 and through the orifice 18 on the annulus stent 10. This is repeated for the second screw 52, after which the suture 40 is secured. One or more surgical sutures 40 are placed at about equal distances along the sides of the aperture 44 in the disc annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 in such a fashion that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable but permanent non-biodegradable forms may be utilized. This method should decrease the strain on the disc annulus [40] 42 adjacent to the aperture 44, precluding the tearing of the sutures through the disc annulus [40] 42.

Paragraph starting at page 13, line 1 extending to line 4:

[050] It is anticipated that fibroblasts will engage the fibers of the polymer or fabric of the intervertebral disc stent 10, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

Paragraph starting at page 13, line 5 extending to line 15:

[051] In an additional embodiment, as shown in [Figures] FIGs. 10A-B, a flexible bladder 60 is attached to the lower surface 30 of the annulus stent 10. The flexible bladder 60 comprises an internal cavity 62 surrounded by a membrane 64, where the membrane 64 is made from a thin flexible biocompatible material. The flexible bladder 60 is attached to the lower surface [28] 30 of the annulus stent 10 in an unexpanded condition. The flexible bladder 60 is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity 62. The exact size of the flexible bladder 60 can be varied for different individuals. The typical size of an adult nucleus is about 2 cm in the semi-minor axis, 4 cm in the semi-major axis, and 1.2 cm in thickness.

Paragraph starting at page 13, line 18 extending to line 23:

[053] In [a preferred] an illustrative embodiment, a hydrogel is injected into the internal cavity 62 of the flexible bladder [28] 60. A hydrogel is a substance formed when an organic polymer (natural or synthetic) is [cross- linked] cross-linked via covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice structure, which entraps water molecules to form a gel. The hydrogel may be used in either the hydrated or dehydrated form.

Paragraph starting at page 14, line 1 extending to line 10:

[054] In a method of use, where the annulus stent 10 has been inserted into the aperture 44, as has been previously described and shown in [Figures 12 A-b]

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FIGs. 12 A-B, an injection instrument, as known in the art, such as a syringe, is used to inject the biocompatible fluid or expansive foam into the internal cavity 62 of the flexible bladder 60. The biocompatible fluid or expansive foam is injected through the annulus stent 10 into the internal cavity 62 of the flexible bladder [28] 60. Sufficient material is injected into the internal cavity 62 to expand the flexible bladder 60 to fill the void in the intervertebral disc cavity. The use of the flexible bladder 60 is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

Paragraph starting at page 14, line 11 extending to line 19:

[055] The surgical repair of an intervertebral disc may require the removal of the entire disc nucleus, being replaced with an implant, or the removal of a portion of the disc nucleus thereby leaving a void in the intervertebral disc cavity. The flexible bladder 60 allows for the removal of only the damaged section of the disc nucleus, with the expanded flexible bladder 60 filling the resultant void in the intervertebral disc cavity. A major advantage of the annulus stent 10 with the flexible bladder 60 is that the incision area in the annulus 42 can be reduced in size[,] as there is no need for the insertion of an implant into the intervertebral disc cavity.

Paragraph starting at page 14, line 20 extending to line 20:

[056] In an alternative method of use, a dehydrated hydrogel is injected into the internal cavity [28] 62 of the flexible bladder 60. Fluid, from the disc nucleus, passes through the semi-permeable membrane 64 hydrating the dehydrated hydrogel. As the hydrogel absorbs the fluid the flexible bladder 60 expands [60], filling the void in the intervertebral disc cavity.

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